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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,274	05/29/2001	Christopher J. Paszty	01017/37428	5510

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EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/867,274	Paszty et al.
Examiner	**Art Unit**
Scott D. Priebe, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 8, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-5, 8-36, and 38-62* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-5, 8-36, and 38-62* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 11, 52-54, drawn to nucleic acid encoding mouse or human cloaked-2 polypeptide, classified in class 536, subclass 23.5.

II. Claims 8 and 10, drawn to a recombinant method of making mouse or human cloaked-2 polypeptide, classified in class 435, subclass 69.1.

III. Claims 9, 13-23, 46-51, 55 and 56, drawn to mouse or human cloaked-2 polypeptide, classified in class 530, subclass 350.

IV. Claim 12, drawn to cell-based assay to identify compound which inhibits activity of mouse or human cloaked-2 polypeptide, classified in class 435, subclass 7.21.

V. Claim 12, drawn to cell-based assay to identify compound which inhibits expression of mouse or human cloaked-2 polypeptide, classified in class 435, subclass 6.

VI. Claims 24-26, 29-36, 38-42, and 44, drawn to an agent (e.g. antibody) which specifically binds mouse or human cloaked-2 polypeptide, classified in class 53, subclass 387.9.

VII. Claims 27 and 45, drawn to hybridoma which produces and antibody which specifically binds mouse or human cloaked-2 polypeptide, classified in class 435, subclass 331.

VIII. Claims 28 and 58, drawn to a method of detecting mouse or human cloaked-2 polypeptide with antibodies, classified in class 435, subclass 7.1.

IX. Claim 43, drawn to a method of treatment with an agent (e.g. antibody) which specifically binds mouse or human cloaked-2 polypeptide, classified in class 424, subclass 139.1.

X. Claims 57 and 59, drawn to a method of treatment with mouse or human cloaked-2 polypeptide, classified in class 514, subclass 2.

XI. Claim 60, drawn to an assay for identifying compounds which bind mouse or human cloaked-2 polypeptide, classified in class 435, subclass 7.1.

XII. Claim 61, drawn to a method of treatment with a nucleic acid encoding mouse or human cloaked-2 polypeptide, classified in class 514, subclass 44.

XIII. Claim 62, drawn to a non-human transgenic animal comprising a nucleic acid encoding mouse or human cloaked-2 polypeptide, classified in class 800, subclass 13.

The inventions are distinct, each from the other because of the following reasons:

Invention I and inventions II, V and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used in any one of the methods of inventions II, V, XII, and also for detecting clones of cloaked-2 nucleic acid or identifying tissue expressing cloaked-2 mRNA.

Inventions I and XIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the transgenic animals can comprise nucleic acid encoding either mouse or human cloaked-2 polypeptide, or any of the derivatives of each embraced by claim 1. The subcombination has separate utility such as the nucleic acid of invention I can be used in any of the methods described in the preceding paragraph which do not involve transgenic animals.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cloaked-2 polypeptide could be produced from mouse or human tissue which endogenously produces it.

Invention III and inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of invention III can be used in inventions X or XI, or to make the antibodies of invention VI.

Inventions III and XIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the transgenic animals can either not express the nucleic acid or express the nucleic acid encoding either mouse or human cloaked-2 polypeptide, or any of the derivatives of each embraced by claim 1. The subcombination has separate utility since the polypeptide of invention III can be used in any of the methods described in the preceding paragraph which do not involve transgenic animals.

Invention VI and inventions VIII, IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case, the binding agents of invention VI can be used in any of the methods of inventions VIII, IX and XI, and for affinity purification of cloaked-2 polypeptide.

Inventions VII and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the antibody be specific for one or some of the human or mouse cloaked-2, or any derivative of these, but not bind others, or cross-reactive with most, or the antibody could be recombinant or polyclonal, i.e. not made in a hybridoma. The subcombination has separate utility such as the methods described above which do not involve hybridomas or require that the antibody be made using a hybridoma.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions I and inventions III, IV, VI, VII, VIII-XI are unrelated; the nucleic acid of invention I is not used in any of the methods of inventions IV, VIII-XI, is not present in the hybridoma of invention VII, and does not share a common structure or function with cloaked-2 protein or agents which bind cloak-2. Invention III and inventions IV-IX, and XII are unrelated; the isolated polypeptide of invention III is not used in any of the

methods of inventions IV, V, VIII, IX, or XII; and does not share a common structure or function with agents which bind cloak-2. Invention VI and inventions II, IV, V, VII, X, XII and XIII are unrelated; the binding agents of invention VI are not used in the methods of inventions II, IV, V, X, or XII, and are not present in the transgenic non-human animal of invention XIII. Inventions VII and XII are unrelated to any claimed method, neither is used in any of the methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each product group is not required for other product groups or method groups where the methods do not use the product, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If

applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

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Art Unit 1632